United States Court of Appeals for the Federal Circuit

92-1170,-1171

WALTER C. FIERS,

Appellant,

v.

MICHEL REVEL and PIERRE TIOLLAIS,

Appellants,

v.

HARUO SUGANO, MASAMI MURAMATSU and TADATSUGU TANIGUCHI,

Appellees.

Judgment

ON APPEAL from the UNITED STATES PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

in CASE NO(S). 101,096

This CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

AFFIRMED

ENTERED BY ORDER OF THE COURT

DATED JAN 19 1993

Francis X. Gindhart

Francis X. Gindhart, Clerk

COSTS: Against Appellants

PRINTING----------$436.00

TOTAL----------$436.00

ISSUED AS A MANDATE: February 18, 1993

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Appellees.

David J. Lee, Fish & Neave, of New York, New York, argued for appellant. With him on the brief were James F. Haley, Jr. and Ivor R. Elrifi. Roger L. Browdy, Browdy & Neimark, of Washington, D.C., argued for appellants.

Nels T. Lippert, White & Case, of New York, New York, argued for appellees.

Appealed from: U.S. Patent & Trademark Office
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DECIDED: January 19, 1993

Before MICHEL, Circuit Judge, COWEN, Senior Circuit Judge, and LOURIE, Circuit Judge.

LOURIE, Circuit Judge.

Walter C. Fiers, Michel Revel, and Pierre Tiollais appeal from the June 5, 1991 decision of the Patent and Trademark Office Board of Patent Appeals and Interferences, awarding priority of invention in a three-way interference proceeding, No. 101,096, to Haruo Sugano, Masami Muramatsu, and Tadatsugu Taniguchi (Sugano). We affirm.

BACKGROUND

This interference among three foreign inventive entities relates to the DNA[1] which codes for human fibroblast beta-interferon (ß-IF), a protein that promotes viral resistance in human tissue. It involves a single count which reads:

> A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide.

The parties filed U.S. patent applications as follows: Sugano on October 27, 1980, Fiers on April 3, 1981, and Revel and Tiollais (Revel) on September 28, 1982.[2] Sugano claimed the benefit of his March 19, 1980 Japanese filing date, Revel claimed the benefit of his November 21, 1979 Israeli filing date, and Fiers sought to establish priority under 35 U.S.C. § 102(g) based on prior conception coupled with diligence up to his British filing date on April 3, 1980.[3]

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[1] DNA is deoxyribonucleic acid, a generic term encompassing the many chemical materials that genetically control the structure and metabolism of living things.

[2] Revel assigned his application to Yeda Research and Dev. Co. Ltd. The real party in interest in the Fiers application has been indicated to be Biogen, Inc. The real party in interest in the Sugano application has been indicated to be Juridical Foundation, Japanese Foundation for Cancer Research.

[3] 35 U.S.C. § 102 provides in pertinent part:

> A person shall be entitled to a patent unless . . .
> (g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable

(continued...)

Sugano's Japanese application disclosed the complete nucleotide sequence of a DNA coding for ß-IF and a method for isolating that DNA.[4/] Revel's Israeli application disclosed a method for isolating a fragment of the DNA coding for ß-IF as well as a method for isolating messenger RNA (mRNA) coding for ß-IF, but did not disclose a complete DNA sequence coding for ß-IF.[5/] Fiers, who was working abroad, based his case for priority on an alleged conception either in September 1979 or in January 1980, when his ideas were brought into the United States, coupled with diligence toward a constructive reduction to practice on April 3, 1980, when he filed a British application disclosing the complete nucleotide sequence of a DNA coding for ß-IF. According to Fiers, his conception of the DNA of the count occurred when two American scientists, Walter Gilbert and Phillip Sharp, to whom he revealed outside of the United States a proposed method for isolating DNA

[3/](...continued)
diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

[4/] Sugano's method involved the preparation of two populations of radioactivity-labelled cDNA probes prepared from the mRNA of fibroblast cells. One population of probes was prepared from the mRNA of induced fibroblast cells and the other population from the mRNA of non-induced cells. These probes were then exposed to a cDNA library prepared from induced cells, and the clones that only hybridized with the first probe were selected. The selected clones were then used as probes to select the full-length DNA sequence encoding ß-IF, which was then sequenced.

[5/] Revel's method involved preparing a cDNA library of clones from the mRNA of cells induced to produce ß-IF, screening each clone for hybridization to mRNA from induced cells, eluting the hybridized mRNA, and assaying the eluted mRNAs for ß-IF activity.

coding for ß-IF brought the protocol back to the United States.[6] Fiers submitted affidavits from Gilbert and Sharp averring that, based on Fiers' proposed protocol, one of ordinary skill in the art would have been able to isolate ß-IF DNA without undue experimentation.[7] On February 26, 1980, Fiers' patent attorney brought into the United States a draft patent application disclosing Fiers' method, but not the nucleotide sequence for the DNA.

The Board awarded priority of invention to Sugano, concluding that (1) Sugano was entitled to the benefit of his March 19, 1980 Japanese filing date,[8] (2) Fiers was entitled to the benefit of his April 3, 1980 British filing date, but did not prove conception of the DNA of the count prior to that date, and (3) Revel was not

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[6] Fiers presented his protocols and progress to date toward isolating DNA coding for ß-IF at a September 21, 1979 meeting in Paris at which Sharp and Gilbert were present. Sharp and Gilbert returned to the United States on September 23 and 24, respectively. Fiers made a second presentation in Martinique on January 12, 1980. Gilbert and Sharp were both present and returned to the United States on January 15 and 17, respectively. On March 25, 1980, Fiers disclosed by telephone to his patent attorney that he had determined the entire nucleotide sequence of a DNA coding for ß-IF. Fiers presented that nucleotide sequence along with a protocol for preparing the complete DNA in Switzerland on March 28, 1980. Fiers and his attorney worked from March 31 until April 2 in Ghent drafting the final portion and claims of the British application that Fiers filed on April 3, 1980.

[7] Fiers' proposed protocol involved preparing a cDNA library from the mRNA of cells induced to produce ß-IF mRNA, and screening the cDNA library for a cDNA that, when introduced into a cell, would cause it to display ß-IF activity.

[8] Sugano also claimed the benefit of an October 30, 1979 Japanese filing date which the Board denied. Sugano does not challenge that determination on appeal.

entitled to the benefit of his November 21, 1979 Israeli filing date. The Board based its conclusions on the disclosure or failure to disclose the complete nucleotide sequence of a DNA coding for ß-IF.

DISCUSSION

Fiers' Case for Priority

The Board held that Fiers failed to establish conception in the United States prior to his April 3, 1980 British filing date. Specifically, the Board determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA, did not establish conception, since "success was not assured or certain until the [ß-IF] gene was in fact isolated and its sequence known." The Board relied on our opinion in Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), in which we addressed the requirements necessary to establish conception of a purified DNA sequence coding for a specific protein. Accordingly, the Board held that Fiers was entitled only to the benefit of his April 3, 1980 British application date because only that application disclosed the complete nucleotide sequence of the DNA coding for ß-IF. That date was subsequent to Sugano's March 1980 Japanese priority date.

Fiers argues that the Board erroneously determined that Amgen controls this case. According to Fiers, the Board incorrectly

interpreted Amgen as establishing a rule that a DNA coding for a protein cannot be conceived until one knows the nucleotide sequence of that DNA. Fiers argues that this court decided Amgen on its particular facts and that this case is distinguishable. Fiers' position is that we intended to limit Amgen to cases in which isolation of a DNA was attended by serious difficulties such as those confronting the scientists searching for the DNA coding for erythropoietin (EPO), e.g., screening a genomic DNA library with fully degenerate probes. According to Fiers, his method could have been easily carried out by one of ordinary skill in the art.[9/] Fiers also argues that Amgen held that a conception of a DNA can occur if one defines it by its method of preparation. Fiers suggests that the standard for proving conception of a DNA by its method of preparation is essentially the same as that for proving that the method is enabling. Fiers thus urges us to conclude that since his method was enabling for the DNA of the count, he conceived it in the United States when Gilbert and Sharp entered the country with the knowledge of, and detailed notes concerning, Fiers' process for obtaining it.

[9/] Fiers' method involved screening a cDNA library which he maintains is smaller and less complex than a genomic DNA library. Fiers also contends that his screening techniques were routine to those skilled in the art, while those skilled in the art lacked experience screening with fully degenerate probes. Fiers also notes that, in contrast to the situation with EPO in which erroneous amino acid sequence information had been published, the first thirteen amino acids of ß-IF were known to the art.

Conception is a question of law that we review de novo. Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 USPQ 81, 87 (Fed. Cir. 1986) (citing Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd, 731 F.2d 831, 837, 221 USPQ 561, 565 (Fed. Cir. 1984)). Although Amgen was the first case in which we discussed conception of a DNA sequence coding for a specific protein, we were not writing on a clean slate. We stated:

> Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed chemical structure of the gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.

927 F.2d at 1206, 18 USPQ2d at 1021. We thus determined that, irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.

Fiers' attempt to distinguish Amgen therefore is incorrect. We also reject Fiers' argument that the existence of a workable method for preparing a DNA establishes conception of that material. Our statement in Amgen that conception may occur, inter alia, when one is able to define a chemical by its method of preparation

requires that the DNA be claimed by its method of preparation. We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process. Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.

The present count is to a product, a DNA which codes for ß-IF; it is a claim to a product having a particular biological activity or function, and in Amgen, we held that such a product is not conceived until one can define it other than by its biological activity or function. The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they had made their inventions and before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans. While one does not need to have carried out one's invention before

filing a patent application, one does need to be able to describe that invention with particularity.

Fiers has devoted a considerable portion of his briefs to arguing that his method was enabling. The issue here, however, is conception of the DNA of the count, not enablement. Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention. See 35 U.S.C. § 112 (1988); Amgen, 927 F.2d at 1212, 18 USPQ2d at 1026. Since Fiers seeks to establish priority under section 102(g), the controlling issue here is whether he conceived a DNA coding for ß-IF, not whether his method was enabling.

We conclude that the Board correctly decided that conception of the DNA of the count did not occur upon conception of a method for obtaining it. Fiers is entitled only to the benefit of his April 3, 1980 British filing date, since he did not conceive the DNA of the count under section 102(g) prior to that date.

Revel's Case for Priority

Revel bears the burden of proving entitlement to the benefit of his earlier-filed Israeli application date. Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1713 (Fed. Cir. 1988). To meet this burden, Revel must prove that his application meets the requirements of 35 U.S.C. § 112, first paragraph, Bigham v. Godtfredsen, 857 F.2d 1415, 1417, 8 USPQ2d 1266, 1268 (Fed. Cir. 1988) (citing Cross v. Iuzika, 753 F.2d 1040, 1043, 224 USPQ 739, 741 (Fed. Cir. 1985)), which provides in pertinent part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same . . . .

Revel thus must show that the Israeli application contains a written description of the DNA of the count and that it is enabling.

The Board held that Revel's Israeli application did not contain a written description of a DNA coding for ß-IF since it did not disclose the nucleotide sequence or "an intact complete gene." The Board, in denying Revel's request for reconsideration, rejected the argument that it is only necessary to show some correspondence between the language in the count and language in the Israeli application to satisfy the written description requirement. The Board stated:

> Moreover, what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed. The test for sufficiency of support is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." As is apparent from our decision, we found the description in Revel's Israeli application inadequate to reasonably convey to the artisan that Revel was in possession of the invention of beta-interferon DNA [citations omitted].

Relying on Amgen, the Board concluded that the Israeli application was not enabling since Revel had not yet conceived the DNA of the count and "[l]ogically, one cannot . . . enable an invention that has not been conceived." Slip op. at 13.

Revel argues that the disclosure of his Israeli application satisfies the written description requirement because it contains language of similar scope and wording to that of the count. Revel cites the following passages from the Israeli application:

> The invention thus concerns also said purified m-RNAs which comprises normally up to 900-1000 nucleotides . . .. In the same manner it also concerns the corresponding c-DNA which can be obtained by transcription of said RNAs [emphasis added];
>
> It is a further object of the present invention to provide a process for the isolation of genetic material (DNA) containing the nucleotide sequence coding for interferon in human cells.

Revel points to a claim in the original Israeli application that corresponds substantially to the language of the count.[10/] According to Revel, since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement. Revel thus urges that only similar language in the specification or original claims is necessary to satisfy the written description requirement.

We disagree. Compliance with the written description requirement is a question of fact which we review for clear error. See Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); Utter, 845 F.2d at 998, 6 USPQ2d at 1714.

[10/] Claim 22 of Revel's original Israeli application reads:

> The DNA coding for a polypeptide having interferon activity insertable in a vector, such as plasmid PBR-322, and having up to 900-1000 nucleotides.

On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must "reasonably convey[] to the artisan that the inventor had possession at that time of the . . . claimed subject matter." Slip op. at 3 (citing Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1117).

An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. Revel's specification does not do that. Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for ß-IF.[11/] A bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA. Revel's argument that correspondence between the language of the count and language in the specification is sufficient to satisfy the written description requirement is unpersuasive when none of that language particularly describes the DNA.

[11/] According to Fiers, Revel's Israeli application also fails the written description requirement because the mRNA disclosed in the application encodes a protein weighing 23,000 daltons which is interleukin-6, not ß-IF. The Board did not premise its decision on this point, and, since we determine that Revel's application does not describe the DNA of the count, we need not reach it either.

As we stated in Amgen and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.

Because the count at issue purports to cover all DNAs that code for ß-IF, it is also analogous to a single means claim, which has been held not to comply with the first paragraph of section 112. See In re Hyatt, 708 F.2d 712, 218 USPQ 195, 197 (Fed. Cir. 1983) ("the enabling disclosure of the specification [must] be commensurate in scope with the claim under consideration.") Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.

The Board's determination that the Israeli application does not contain a written description of a DNA coding for ß-IF was thus not clearly erroneous. The Board correctly determined that Revel is not entitled to the benefit of his November 1979 Israeli application since it fails to satisfy the written description requirement of section 112.[12/]

[12/] In light of our disposition of the written description requirement question, we do not address whether Revel's Israeli application satisfies the enablement requirement.

Sugano's Case for Priority

The Board held that Sugano established entitlement to his March 19, 1980 Japanese filing date because the disclosure of his Japanese application contains the complete and correct sequence of the DNA which codes for ß-IF, along with a detailed disclosure of the method used by Sugano to obtain that DNA. The Board rejected Fiers' argument that Sugano's March 1980 application is not enabling, since Fiers presented only attorney argument that was "unsupported by competent evidence, entitled to little or no weight and [was] unpersuasive in any event." Slip op. at 12.

Fiers argues that Sugano failed to prove that his application is enabling because he did not produce extrinsic evidence showing enablement. Fiers also argues that the Board erroneously imposed a burden on him to show that Sugano's application is not enabling when, in fact, Fiers had no right to submit rebuttal evidence once Sugano elected to rely solely on his Japanese application.

Enablement is a question of law that we review de novo. Amgen, 927 F.2d at 1212, 18 USPQ2d at 1026. Enablement requires that the application "'contain a description that enables one skilled in the art to make and use the claimed invention.'" Id., (citing Atlas Powder Co. v. E.I. duPont De Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984)). "[A] specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the

subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971). "[A]ny party making the assertion that a U.S. patent specification or claims fails, for one reason or another, to comply with § 112 bears the burden of persuasion in showing said lack of compliance." Weil v. Fritz, 601 F.2d 551, 555, 202 USPQ 447, 450 (CCPA 1979). Thus, once the examiner accepted the sufficiency of Sugano's specification, Sugano had no further burden to prove by extrinsic evidence that his application was enabling; the Board correctly determined that it was Fiers (or Revel) who then had to prove that Sugano's application was not enabling. Even if Fiers had no opportunity to cross-examine Sugano because Sugano elected to stand on his filing date, Fiers had other opportunities, including during the motion period, to challenge Sugano's entitlement to his Japanese application filing date. Thus, he did not lack opportunity to challenge.

We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for ß-IF and the Board did not err in determining that Fiers presented no convincing evidence impeaching the truth of the statements in Sugano's patent specification. We also conclude that Sugano's application satisfies the written

description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for ß-IF and thus "convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for ß-IF]." See Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1117. The Board correctly determined that Sugano's March 19, 1980 Japanese application satisfies the requirements of section 112, first paragraph, and that Sugano thus met his burden to establish entitlement to that filing date.

CONCLUSION

The Board correctly awarded priority of invention to Sugano. Accordingly, the decision of the Board is

AFFIRMED.